PHARMACEUTICALS

Industry Sector Analysis [ISA]

Regions: ANESA; Africa; Southern Africa; AFDB

Country: South Africa

Industry: Health TechnologiesSector: Drugs/Pharmaceuticals

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SUMMARY

More than a \$1 billion worth of pharmaceuticals is sold in South Africa annually and the market has been averaging a healthy 4.8 percent growth rate over the past few years. Tariff rates are relatively low and import penetration is significant at 35 percent. Imports are growing at a faster rate than the overall market (9.3 percent) and the prospects for further inroads is great, especially as the South African authorities, the private sector, and international development bodies begin to coordinate their strategy to combat the HIV/AIDS pandemic.

This report does not specifically touch on anti-retroviral pharmaceuticals because much work is left to arrive at a sustainable policy framework to combat HIV/AIDS. The result of the current debate will effect the outlook for pharmaceutical imports. Nevertheless, the huge impact of HIV/AIDS on society assures a prominent role for pharmaceutical manufacturers who produce medicines to combat the disease.

The market is the most advanced in Africa and receptive to imported products. In the latest survey, 148 companies were identified as manufacturing and/or distributing approved pharmaceuticals in South Africa. Roughly speaking market share is divided equally between South African, U.S. and European manufacturers. It is a very competitive market, and one that shifts significantly in response to the latest worldwide developments.

Market Overview

According to market researchers, there are no dominant firms in the industry; none of the players control a major share of the market. Secondly, there is considerable market turbulence as firms introduce new products and gain temporary leadership before being displaced in their turn.

The corporate ownership in the South African pharmaceutical market follows the trend that exists globally: with European. American and South African owned

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companies commanding a significant presence in this market (Table 1). The ranking and market strength of various players varies according to innovations that they bring into the market.

Out of the total of 148 companies that operated in the South African pharmaceutical market in 1999, 87 concentrated the bulk of their business in supplying the private sector and 61 competed mainly for the public sector market. Market leaders among the top 10 manufacturing companies in the public sector were Swiss and German, South African and American companies were strong in the private sector.

PERCENTAGE SA MARKET SHARES BY NATIONALITY OF CORPORATE OWNERSHIP

Private Pharmacy 1999 Market Share Public Sector 1999 Market Share
South Africa 29.5 USA 25
USA 26.9 South Africa 23.6
Germany 13.8 Germany 17.3
UK 11.8 Switzerland 15.3
Switzerland 10.4 UK 8.8
France 4.1 Denmark 5
Denmark 1.9 France 3.5
Belgium 1.2 Belgium 0.4
New Zealand 0.2 New Zealand 0.2
India 0.1 Netherlands 0.1
Other 0.1 India 0.8
Total 100 Total 100

Table 1: IMS IMS - Intercontinental Medical Statistics Health 1999

Market share varies across corporate market shareholders. Of the 20 South African firms, only four account for bulk private sales (92% of local company sales to the private pharmacy market). Of the 20 US firms, 12 have significant sales. Of around 12 German companies, 8 have significant sales and 6 of 12 UK firms are large, as are 3 of six Swiss companies.

The major pharmaceuticals distributors are the buying groups, dispensing doctors, pharmacists with wholesale licenses and wholesalers. As a result of this, a number of companies or associations of companies, have their own distribution divisions that are affiliated to these associations.

Dispensing occurs via private channels, dispensing doctors, retail pharmacies, retail chains, private and public institutions, industrial clinics, private and government hospitals

Table 2 shows estimates of industry sales and how they are divided across the various channels.

Pharmaceutical Market Estimates 1998 2000 2002 \$million Distribution % \$million Distribution % \$million Distribution % Pharmacy Retail

Public

Dispensing Doctors Private Hospitals & Clinics Total Ethical Unscheduled Institutional CMS and Other* 512.1 480.3 31.8 273.1 89.6 183.6 156.7 133.6 1075.5 48 94 6 25 33 67 15

12

100 606.0

570.9

35.1

292.5

94.0

198.5

179.1

```
153.7
1231.3 49
94
6
24
32
68
15
12
100 697.00
659.7
37.3
310.4
97.0
213.4
194.0
173.1
1374.6 51
94
6
23
32
68
14
12
100
Table 2: IMS Health 1999 (Estimates as at 1999)
OTHER includes direct sales to certain provincial hospitals
MARKET SIZE TABLE FORMAT (US DOLLARS - MILLIONS)*
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Estimated

% Growth 1999 2000 2001 Next 2 Year

Import Market 319.6 349.3 381.8 9.3%

Plus: Local Production 647.0 678.0 710.5 4.8%

Less: Exports 102.9 118.4 136.3 15.1%

Total Market 863.3 908.9 956.0 10%

Imports from U.S. 31.3 34.2 37.4 9.8%

Exchange Rates \$1 = R6.7

Estimated Future Inflation Rate: 5%

1999 Import Market Share (Percent for US and Major Competitors):

Germany: 17.3%; United Kingdom: 16.5%; Switzerland: 13.2%; France 10.1%; United

States: 9.8%; Belgium: 6.2%.

SOURCE: Industrial Development Corporation (IDC) 1999

* The statistics are based on the independent study estimates by the Industrial Development Corporation (IDC). According to IMS Health statistics, the market is somewhat larger.

Sales Prospects

Table 3 (below) shows the leading 10 therapeutic classes in the private and public sectors by sales value as percentages of the total markets. Analysts predict the market to follow the same trend over the next three years. The leading ten therapeutic classes in the private sector show similar tendencies as in the global market.

LEADING TEN THERAPEUTIC CLASSES

PRIVATE SECTOR PUBLIC SECTOR

Classes Market Size 1999 (%) Classes Market Size 1999 (%)

Non-Narcotic Analgesics

Anti-Depressants

Antirheumatic Non Steroidal

Cold Preparations

Cholesterol and Trigly Reducers

Antiulcerants

Ace Inhibitors

Expectorants

Cephalasporins and Combinations

Tropical Nasal Preparations

Total 9.3

- 3.5
- 3.1
- 2.9
- 3.2
- 2.8
- 2.3
- 2.1 2.1
- 2.0

33.3 Cephalasporins and Combinations

Ace Inhibitors Plain

Anti-Epileptics TB Drugs Fluoroguinolones Hormonal Contraceptive syst. Med/Narrow Spectrum Penicillin's Antidiabetics Antipsychotics **Broad Spectrum Penicillins** Total 3.4 5.6 5.4 5.7 2.8 4.8 3.2 3.8 3.3 2.8 40.8

Table 3: IMS Health 1999

Market Trends

The medicinal and pharmaceutical preparations sub-sector, which accounts for about 6% of the chemical sector's total output, consists mainly of the manufacture, fabrication and processing of drugs and medicines, including biological products such as bacterial and viral vaccines, serums and plasmas. Also included are medicinal chemicals and botanical products such as antibiotics, quinine, strychnine, sulphur drugs, opium and derivatives, adrenaline, caffeine, codeine derivatives, vitamins and pharmaceutical preparations for humans and veterinary use.

Both private consumption expenditure and intermediate users play a very significant role in the domestic demand for medicinal andpharmaceutical products. Accordingly, the sub-sector's prospects are highly dependent on the socio-demographic trends such as population growth, income distribution, access to health facilities and general public awareness, as well as on the overall performance of the manufacturing industries with which it has close linkages.

On the intermediate demand side, the main consumers are the medical, dental and other health and veterinary services, which together account for more than 30% of the overall intermediate consumption. The agricultural sector is also an important component of demand, especially where vaccines for livestock are concerned. Substantial amounts of such vaccines are also purchased by households for use on domestic pets.

Average growth in the domestic production is expected to slow down to some 4.8% p.a. over the period to 2001. This may be ascribed to very low levels of tariff protection, at 0.2% on the import-weighted basis, and thus fierce competition from abroad. Accordingly, import growth is forecast at 9.3% p.a. and the sub-sector's import propensity is likely to reach 43% level by 2001 (Table 4).

MEDICAL AND PHARMACEUTICAL PREPARATIONS

1996 1991–1996 1997 1998 1999 2000 2001 1997-2001 \$MIL AVERAGE ANNUAL PERCENTAGE CHANGE, REAL Domestic Production 617.3 6.7 2.0 5.0 6.2 4.8 6.0 4.8 Demand

- domestic goods
- imported goods 820.4

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528.1
292.4
3.8 5.4
3.2
9.4 4.5
1.7
9.1 6.5
3.7
11.0 3.9
1.2
7.9 5.9
3.8
8.8 5.3
2.7
9.3
Exports 89.4 9.8 11.7 11.2 11.7 9.9 15.1
RATIOS %
Import penetration
Export propensity 35.6
14.5 37.0
18.6 38.6
19.8 40.3
20.7 41.8
22.1 43.0
22.9
Table 4: Industrial Development Corporation (IDC)
Exchange Rate: $1=R6.7
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At 6.7% p.a. during the period 1991 to 1996, average growth in sub-sectoral production was the second highest in the chemical sector. Locally produced items cater for 64% of the domestic requirements but, in response to the reduced tariff protection, imports consist largely of medicaments which originate mainly from Switzerland, the United Kingdom, Germany, the USA and France.

Intermediate inputs are sourced from within the sub-sector itself (10% of total costs), as well as from the sub-sectors that produce basic chemicals (9%) and other chemical products (6%). Furthermore, 15% of intermediate costs are spent on packaging materials, including paper, plastics and glass. The sub-sector is also relatively labor intensive, with labor costs representing 27% of the overall cost structure.

After a sluggish growth in private consumption expenditure on pharmaceutical products over the past seven years, household demand is expected to increase during the forecast period. In addition, government's primary health care strategy, which focuses on improved access to health facilities, particularly in rural areas, as well as more affordable medicines, will impact positively on this sub-sector.

Import Market

The largest pharmaceutical exporter to South Africa with 17.3% share of this country's total imports is Germany, followed by the UK (16.6%), Switzerland (13.2%), France (10.1%) and USA (9.8%). This is not unexpected since these are the countries that are responsible for the bulk of medical advances and most pharmaceutical research and development work on which these advances depend.

In line with Government policy of providing affordable, quality healthcare for all South Africans, duties on all finished pharmaceutical products and most

pharmaceutical intermediates were lifted in 1994. Over the last five years, the pharmaceutical industry has experienced a significant growth of sales, both to the state and private sector. Analysts look at this as a normal trend since the South African market in too small to justify wide range of pharmaceuticals domestically.

The Department of Trade and Industry believes that South Africa has the human and technical potential to develop world-class manufacturing of active pharmaceutical ingredients (APIs) and formulated pharmaceutical products, in partnership wit foreign companies.

The negative effect of the low levels of tariff protection on domestic production of pharmaceuticals is expected to enhance competition from abroad. Accordingly, import growth is forecast at 9.3% p.a. up to 2001.

Table 5 (below) lists the largest South African pharmaceuticals trade partners.

SOUTH AFRICAN PHARMACEUTICAL IMPORTS Imports from 14 Largest Trade Partners (R Million)

Countries 1998 1999 2000 (projected) India 41.12 46.74 \$7.6 Japan 44.17 66.55 \$10.9 Australia 66.05 66.18 \$10.8 Sweden 68.23 67.70 \$11.0 Denmark 68.37 88.30 \$14.4 Ireland 108.45 119.27 \$19.5 Netherlands 104.01 122.20 \$19.9 Italy 137.86 183.45 \$29.9 Belgium 178.75 226.57 \$37.0 USA 333.98 347.76 \$56.7 France 325.45 415.24 \$67.7 Switzerland 392.02 406.91 \$66.4 UK 495.14 517.86 \$84.5 Germany 486.39 715.12 \$116.7

Table 5: Department of Trade and Industry (Pretoria) 1999 Projected import figures for 2000 are converted to dollars. Exchange rate \$=R6.7

HS codes for leading imports are listed below:

- 1) 2936 Provitamins and vitamins, natural or synthetic this heading contains 11 individual tariff lines, covering all provitamins, vitamins and natural vitamins concentrates. Imports under this heading were nearly \$20.9million in 1998. Vitamin E and its derivatives account for 30% of imports in this group, followed by Vitamin C (17% of total). The major suppliers of vitamins to South Africa are Switzerland, Germany and the UK.
- 2) 2940 Chemically pure sugars and their derivatives this group excludes chemically pure glucose, frucose, sucrose, maltose and lactose, glycosides and derivatives of alkaloids. All products classified under this heading are duty free. Imports under this heading were worth \$0.34m in 1998.
- 3) 2941 Antibiotics this heading consists of six lines which carry no duty total imports in 1998 was \$17.16 million, with major suppliers being USA, Italy, UK, Spain and China. Imports from Germany accounted for 4,4% of total imports reported under heading 2941. Penicillins and their derivatives account for one-third of all imports under this heading.
- 4) 3001 to 3006 Pharmaceutical Products This heading consists of six headings with products which are duty free except for bandages and gauze which attract a 10% duty. Imports in this category amounted to over \$0.04milion in

1998.

Imports of medicaments in a "in measured doses/ ready for retail sale" form (3004) were worth nearly \$0.37milliom in 1998. This import has been growing an average of rate of 45% per year over the last four years (rate not adjusted for currency fluctuations).

Competition

Innovation in the pharmaceutical industry plays a significant role for companies to retain their market share. New products are continuously introduced which command a better market demand. Competitive commercial success depends, therefore, on the ability of individual companies to produce innovations and better products that the patient and the medical profession demand.

As an indicator of the entry level in the market place, the third top company in 1997 in the state market was ranked only 17th in 1988, and the third ranked firm in the private sector in 1989 had fallen to 6th by 1998, etc (Table 2). The top spot in the pharmaceutical industry is very slippery because of innovation.

SA PHARMACEUTICAL MARKET: FIRM RANKING 1989 AND 1998 (PRIVATE) 1988 AND 1997 (PUBLIC)

PRIVATE PHARMACY PUBLIC SECTOR Company Rank 1998 Rank 1989 Share 1998 (%) Company Rank 1997 Rank 1988 Share 1997 (%) A 1 1 17.2 AA 1 1 12.0 B 2 2 8.0 BB 2 2 11.4 C 3 4 5.5 CC 3 17 6.6 D 4 7 4.4 DD 4 7 6.1 E 5 5 4.2 EE 5 3 5.4 F 6 3 4.2 FF 6 11 4.7 G 7 8 4.0 GG 7 9 4.7 H 8 9 4.0 HH 8 10 4.2 I 9 13 3.5 II 9 8 4.1 J 10 6 3.5 JJ 1 12 3.9 Table 6: IMS Health 1998

Aglance at the market share columns in table 6 and 7 shows how dependent firms are on only one or two products for their commercial existence. The market "churn" of firms is closely related to the turbulence caused by product innovation.

SA PHARMACEITICAL MARKET: PRODUCT RANKING 1989 AND 1998 (PRIVATE) 1988 AND 1997 (PUBLIC)

PRIVATE PHARMACY PUBLIC SECTOR Company Rank 1989 Rank

1998 Share 1989 (%) Company Rank 1988 Rank 1997 Share 1988 (%) a 1 1 1.5 aa 1 61 2.7 b 2 60 1.3 bb 2 12 2.4 c 3 9 1.3 cc 3 9 1.7 d 4 4 1.2 dd 4 159 1.4 e 5 42 1.0 ee 5 90 1.4 f 6 69 0.9 ff 6 1323 1.3 g 7 224 0.9 gg 7 1339 1.3 h 8 85 0.8 hh 8 1157 1.3 i 9 24 0.8 ii 9 44 1.2 i 10 2 0.7 ji 10 1462 1.2 Table 7: IMS Health 1998

Table 7 illustrates how in the last ten years only four products in the top ten in 1989 were still in the top ten 1998 (a, c, d and j) in the private market, and only one products (cc) held its position in the state sector (1988 to 1997). Superior products have overtaken all the other 15 and their commercial positions have plunged.

Market Access .

Market analysts have cited the following factors as posing difficulties to companies who want to make inroads into the pharmaceutical market:

- · The product would have to be approved by the Medicines Control Council (MCC), a body that ensures that drugs are safe, effective and meet approved standards and specifications.
- · It would have to be registered. The product registration process takes a long time (12 36 months), depending on the need and classification as essential drugs,
- \cdot Competition with existing players in the private market, who supply the same drug,
- · The normal tender procedures will have to be followed where the company intends to supply to government. This requires that they have a presence in South Africa in the form a distributor, licensee or a manufacturing facility, which will also look into how the medicine is relinquished to both dispensers and end users.

End User Analysis

South Africa has a population of about 40 million people. Approximately 90 percent of this number is located in the areas surrounding Johannesburg, Cape Town, Durban, Pretoria and Port Elizabeth, which represent the country's major areas of economic activity and major consumer markets.

Sources

- 1. Pharmaceutical Manufacturers Association of South Africa (PMA)
- 2. Sunday Times

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